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December 17, 2001

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Re:

Washington, D.C. 20231

U.S. Patent Application No.: 09/825,533

SYSTEM FOR CLINICAL TRIAL SUBJECT COMPLIANCE

Inventors: Michael R. Hufford et al.

Filed: April 2, 2001 Our Ref. No.: IVQ-002

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

- Information Disclosure Statement; 1.
- 2. PTO Form 1449:
- Copies of references cited in PTO Form 1449; and 3.
- A Return Postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

I hereby certify that this correspondence is deposited with the . United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on:

December 17, 2001

David J. Rikkers, Reg. No. 43,882

Respectfully submitted, LAHIVE & COCKFIELD, LLP

David J. Rikkers

Registration No. 43,882 Attorney for Applicants

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Michael R. Hufford et al.

Serial No.: 09/825,533

Filed: April 2, 2001

For: SYSTEM FOR CLINICAL TRIAL-SUBJECT

**COMPLIANCE** 

Attorney Docket No.: IVQ-002

Commissioner for Patents Washington, D.C. 20231

Group Art Unit: 2171

Examiner:

Technology Center 2100

Certificate of First Class Mailing (37 CFR §1.8(a))

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on the date set forth below.

December 17, 2001

Date of Signature and of Mail Deposit

By:

David J. Rikkers

Registration No. 43,882 Attorney for Applicants

## INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Applicants and their Attorney are aware of the following publications and information, listed on the attached PTO Form 1449, and in accordance with 37 CFR §1.97 hereby submit these publications for the Examiner's consideration. A copy of each cited publication is enclosed.

Serial Number: 09/825,533 Page -2- Group Art Unit: 2171

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted, LAHIVE & COCKFIELD, LLP

David J. Rikkers

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Date: December 17, 2001

KJC/DJR/ham Enclosures

	APPLICANT FACSIMILE OF FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE	ATTY DOCKET NO	SERIAL NO.	
	REV 7-80	PATENT AND TRADEMARK OFFICE	IVQ-002	09/825,533	
ı	LIST OF PUBLICATIONS CITED	BY APPLICANT	APPLICANT		
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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A1	Des. 247,251	02/78	Napoli	D24	17	_
	A2	4,262,632	04/81	Hanton et al.	119	1	7
	А3	4,343,375	10/82	Colburn et al.	128	782	n vic
	A4	4,367,752	01/83	Jimenez et al.	128	689	May the
	A5	4,543,955	10/85	Schroeppel	128	635	0
	A6	4,566,461	01/86	Lubell et al.	128	668	C TO
	Α7	4,592,018	05/86	Wiegman	365	63	le,
	A8	4,686,624	08/87	Blum et al.	364	415	10
	A9	4,803,625	02/89	Fu et al.	364	413.03	10
	A10	4,844,076	07/89	Lesho et al.	128	631	
	A11	4,883,063	11/89	Bernard et al.	128	670	-
	A12	4,909,260	03/90	Salem et al.	128	721	
	A13	4,966,154	10/90	Cooper et al.	128	671	
	A14	4,974,601	12/90	Tranjan et al.	128	696 ·	
	A15	4,975,842	12/90	Darrow et al.	364	413.02	
	A16	4,987,897	01/91	Funke	128	419 PG	
	A17	5,002,064	03/91	Allain et al.	128	710	
	A18	5,063,937	11/91	Ezenwa et al.	128	723	
	A19	5,078,134	01/92	Heilman et al.	128	421	-
	A20	5,111,818	05/92	Suzuki et al.	128	644	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	Country	CLASS	SUBCLASS	TRANSLA	TION
							YES	NO
	A21	WO 88/02237 A1	04/88	PCT				
	A22	EP 299667 A1	01/89	EPO				
. //	A23	WO 89/05116 A1	06/89	PCT				
/	A24	FR 2686497 A1	07/93	France			Abstr.	
	A25	WO 94/01049 A1	01/94	PCT				
-	A26	WO 94/13198 A1	06/94	PCT	-	•		
•	A27	WO 94/24929 A1	11/94	PCT				

OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

A28	Bradburn, NM, et al. "Answering Autobiographical Questions: The Impact of Memory and Inference on Surveys" <i>Science</i> 10 Apr 1987;236:157-161
Examiner	Date Considered
EXAMINER:	Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

APPLICANT		

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY DOCKET NO IVQ-002

APPLICANT

SERIAL NO. 09/825,533

LIST OF PUBLICATIONS CITED BY APPLICANT (Use several sheets if necessary)

Michael R. Hufford et al.

April 2, 2001

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			U.S	S. PATENT DOCUMENTS			1009 Center 2100
	B1	5,113,859	05/92	Funke OPE	128	419 PG	9 5
	B2	5,128,552	07/92	Fang et al.	307	66	6 2
	B3	5,131,390	07/92	Sakaguchi et al. JAN 0 8 7002 w	128	632	TE P
	B4	5,137,345	08/92	Waldorf et al.  Bible  Conlan	351	206	22
	B5	5,181,519	01/93	Bible TRADEMARK	128	704	0
	В6	5,197,489	03/93	Conlan	128	782	
	В7	5,199,439	04/93	Zimmerman et al.	128	670	
	B8	5,213,106	05/93	Lerner	128	696	
	В9	5,213,555	05/93	Hood et al.	482	57	
	B10	5,218,969	06/93	Bredesen et al.	128	710	
	B11	5,222,503	06/93	Ives et el.	128	731	
	B12	5,226,424	07/93	Bible	128	696	
	B13	5,226,539	07/93	Cheng	206	534	
	B14	5,228,450	07/93	Sellers	128	711	
	B15	5,253,654	10/93	Thomas et al.	128	779	
• .	B16	5,261,412	11/93	Butterfield et al.	128	672	
	B17	5,271,405	12/93	Boyer et al.	128	672	
	B18	5,275,159	01/94	Griebel	128	633	
	B19	5,280,429	01/94	Withers	364	413.15	
	B20	5,289,824	03/94	Mills et al.	128	696	
	B21	5,307,263	04/94	Brown	364	413.09	
	B22	5,447,164	09/95	Shaya et al.	128	710	
	B23	5,454,376	10/95	Stephens et al.	128	721	<u> </u>
	B24	5,672,154	09/97	Sillén et al.	604	50	
	B25	5,778,882	07/98	Raymond et al.	128	700	
	B26	6,095,985	08/00	Raymond et al.	600	513	

OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

В	27	Collins RL, et al. "Ecological momentary assessment in a behavioral drinking moderation training program" <i>Exp. Clin. Psychopharmacol.</i> 1998 Aug;6(3):306-15					
1 B	28	Cramer, JA et al. "How often is medication taken as prescribed?" JAMA 1989;261:3273-3277					
/, B	29	Eich, E, et al. "Memory for Pain: Relation between Past and Present Pain Intensity" <i>Pain</i> 1985;23:375-379					
/ 1 B	30	Friedman, WJ "Memory for the Time of Past Events" Psychological Bulletin 1993;113(1):44-66					
Examiner	ľ	Date Considered					
EXAMINER:		Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					

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	RADE	MARK STHERS (including Author, Title, Dat	te, Pertinent Pages, Etc.)	500
	C1	Gorin AA, et al. "Recall Biases and Cogr Momentary Assessments" <u>Handbook of</u> NJ. 2001;pp. 405-413	nitive Errors in Retrospective	Self-Reports: A Call for
	C2	Greeno CG, et al. "Binge antecedents in J. Consult. Clin. Psychol. 2000 Feb;68(1		out binge eating disorder"
./	C3	Hyland, ME, et al. "Diary keeping in asth BMJ 20 Feb 1993;306(6876):487-489	ma: comparison of written a	and electronic methods"
/	C4	Karmack TW, et al. "The effects of psych contrasting different measurement and c Society for Psychophysical Research, N 1997. Psychophysiology 1997;34 (Suppl	lata analytic strategies" 37 <sup>th</sup> / orth Falmouth, Massachuset	Annual Meeting of the
	C5	Kamarck TW, et al. "Effects of task strain cardiovascular activity: daily life consequent Health Psychol. 1998 Jan;17(1):17-29	n, social conflict, and emotion	
/	C6	Kamarck TW, et al. "Emotional Support I Daily Life" Abstracts of Papers for 1999 A Activity in Relation to Stress Psychology 1999;6(1):112 (abstract)	Annual Meeting: Paper Sess	sion: Cardiovascular
	C7	Kamarck TW, et al. "The Diary of Ambula Assessment of Psychosocial Influences Methods in Behavioral Medicine (D.S. Kr Associates: Mahwah, NJ. 1998; Chapter	on Ambulatory Cardiovascul rantz and A. Baum, eds.) Lav	ar Activity" Technology and
/	C8	O'Connell KA, et al. "Overcoming the Urg and Late Relapsers" Psychology of Addi		
	C9	O'Connell KA, et al. "Coping in real time: to assess coping with the urge to smoke"	using Ecological Momentar	y Assessment techniques
	C10	O'Connell KA, et al. "Symptom beliefs ar Health. 1990 Jun;13(3):145-51		
/	C11	O'Connell KA, et al. "Reversal theory and highly tempting situations" J. Consult. Cl.		
	C12	O'Connell KA "Why rational people do irr Psychosoc. Nurs. Ment. Health Serv. 19	ational things. The theory of	
/	C13	Paty, J, et al. "The importance of assess stimulus control of smoking" The Experie Disorders in their Natural Settings (DeVr Press. 1992; pp. 347-352	ing base rates for clinical stuence of Psychopathology: In	vestigating Mental
/	C14	Penner, LA, et al. "Individual Differences Personality and Social Psychology 1994;		Mood" Journal of
/	C15	Potocky M, et al. "State-outcome consist approach" J. Consult. Clin. Psychol. 199	ency in smoking relapse cris	es: a reversal theory
	C16	Raynor, DA et al. "The effects of social ir natural environment" 37th Annual Meeting Falmouth, Massachusetts, USA, Oct. 15	offluence on cardiovascular reg of the Society for Psychoph	nysical Research, N.
	C17	Ross, M "Relation of Implicit Theories to	the Construction of Personal	l Histories" <i>Psychological</i>

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Examiner

Review 1989;96(2):341-357

Date Considered

Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

•				Sheet 4 c	of 5	
1	APPLICANT FACSIMILE OF FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE	ATTY DOCKET NO	SERIAL NO.		
	REV 7-80	PATENT AND TRADEMARK OFFICE	IVQ-002	09/825,583	10 XX	
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	JAN O B 2002 &		FILING DATE	GROUP	Co Top '	_
	SAN 0 0 2062 W		April 2, 2001	2171	27/2	

(including Author, Title, Date, Pertinent Pages, Etc.) Schwartz JE, et al. "Does trait coping exist? A momentary assessment approach to the evaluation of traits" J. Pers. Soc. Psychol. 1999 Aug;77(2):360-9 D2 Schwartz JE, et al. "Strategies for analyzing ecological momentary assessment data" Health Psychol. 1998 Jan;17(1):6-16 D3 Shiffman S. "Real-Time Self-Report of Momentary States in the Natural Environment: Computerized Ecological Momentary Assessment" The Science of Self-Report: Implicates for Research and Practice (A. Stone, et al. eds.) Mahwah, NJ: Lawrence Erlbaum Associates. 1989; Chapter 16: 277-296 D4 Shiffman, Saul "Assessing Smoking Patterns and Motives" Journal of Consulting and Clinical Psychology 1993;61(5):732-742 D5 Shiffman S, et al. "Drinking and Smoking: A Field Study of their Association" Annals of Behavioral Medicine 1994; 16(3):203-209 D6 Shiffman S, et al. "Nicotine withdrawal in chippers and regular smokers: subjective and cognitive effects" Health Psychol. 1995 Jul;14(4):301-9 D7 Shiffman S. et al. "First lapses to smoking; within-subjects analysis of real-time reports" J. Consult. Clin. Psychol. 1996 Apr;64(2):366-79 Shiffman S, et al. "Progression from a smoking lapse to relapse: prediction from abstinence D8 violation effects, nicotine dependence, and lapse characteristics" J. Consult. Clin. Psychol. 1996 Oct;64(5):993-1002 D9 Shiffman S, et al. "Temptations to smoke after quitting: a comparison of lapsers and maintainers" Health Psychol. 1996 Nov;15(6):455-61 D10 Shiffman S, et al. "A day at a time: predicting smoking lapse from daily urge" J. Abnorm. Psychol. 1997 Feb;106(1):104-16 D11 Shiffman S, et al. "Remember that? A comparison of real-time versus retrospective recall of smoking lapses" J. Consult. Clin. Psychol. 1997 Apr;65(2):292-300 D12 Shiffman S, et al. "Individual differences in the context of smoking lapse episodes" Addict. Behav. 1997 Nov-Dec;22(6):797-811 D13 Shiffman S, et al. "The Abstinence Violation Effect Following Smoking Lapses and Temptations" Cognitive Therapy and Research 1997; 21(5):497-523 D14 Shiffman S, et al. "The effect of bupropion on nicotine craving and withdrawal" Psychopharmacology (Berl) 2000 Jan;148(1):33-40 D15 Shiffman S, et al. "Dynamic effects of self-efficacy on smoking lapse and relapse" Health Psychol. 2000 Jul;19(4):315-23 D16 Shiffman S, et al. "Comparative efficacy of 24-hour and 16-hour transdermal nicotine patches for relief of morning craving" Addiction 2000 Aug;95(8):1185-95 D17 Stone, AA, et al. "Ecological Momentary Assessment (EMA) in Behavioral Medicine" Annals of Behavioral Medicine 1994;16(3):199-202 D18 Stone, AA, et al. "A comparison of coping assessed by ecological momentary assessment and retrospective recall" J. Pers. Soc. Psychol. 1998 Jun;74(6):1670-80 Stone, AA, et al. "Ecological Momentary Assessment" Well-being: The foundations of Hedonic D19 psychology. Kahneman, Daniel et al. (eds.). Russell Sage Foundation: New York, NY. 1999; pp.26-39 Date Considered Examiner

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Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.